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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,629	01/11/2000	HARALD SEULBERGER	48141	5335

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/462,629	Applicant(s) SEULBERGER ET AL	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.  
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 25 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-14 is/are rejected.  
 7) ☒ Claim(s) 25 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR § 1.114***

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 26 August 2005 has been entered.

### ***Status of the Application***

2. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825.

The amino acid sequences on pages 24-26 do not comply with the sequence rules, because they do not have a sequence identifier in the specification nor are they in the sequence listing, with the exception of "HPPD\_Hv". Applicant's amendment filed on 26 August 2005 does not fully comply with this requirement because it only amends the

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specification to indicate "SEQ ID NO: 2", it does not address the additional sequence disclosures in the specification.

In addition, the specification at page 11, line 9 and 26 contain amino acid sequence disclosures that do not comply with the Sequence Rules.

Failure to comply with these requirements will be considered non-responsive to this Office action.

### ***Claim Objections***

5. Claims 5, 14 and 25 are objected to because of the following informalities:

At claim 5, line 2, "*a Hordeum vulgare*" should be amended to read -- the *Hordeum vulgare* -- in light of Applicant's amendment to claim 1.

At claim 14, line 2, "the DNA sequence" should be amended to read -- the isolated DNA -- in light of Applicant's amendment to claim 1.

At claim 25, line 1, "sequence" should be deleted after "DNA" in light of Applicant's amendment to claim 1.

Appropriate correction is required in these matters of form.

### ***Claim Rejections - 35 USC § 112***

6. Claims 2 and 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because it is unclear who the promoter and DNA are associated. It is suggested that the claim read -- a promoter operably lined to the DNA -

-.

Claim 3 is indefinite because it is unclear if "a CaMV 34S promoter" is further limiting the promoter at claim 2, or encompasses an additional promoter; hence the metes and bounds of the claim are unclear.

7. Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 May 2005. Applicant's arguments filed 26 August 2005 have been fully considered but they are not persuasive.

Applicant claims an isolated DNA encoding *Hordeum vulgare* HPPD (hydroxyphenyl pyruvate dioxygenase).

Applicant describes an isolated DNA from *Hordeum vulgare* encoding the amino acid sequence of SEQ ID NO: 2 and encoding an HPPD enzyme.

Applicant does not describe a genus of isolated DNAs encoding *Hordeum vulgare* HPPD.

Applicant's argument that amending claim 1 to recite "...*Hordeum vulgare*..." overcomes the instant rejection is not found to be persuasive (page 4 of the response filed on 26 August 2005). Claim 1 as amended does not describe a structural feature of the claimed isolated DNA or of the encoded HPPD enzyme. As the instant claims encompass isolated DNAs encoding a genus of *Hordeum vulgare* HPPD enzymes that would have silent mutations and functional mutations including additions and deletions

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to the encoding sequence, Applicant has failed to adequately describe the claimed invention by only describing a single species that falls within the claimed genus. See MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

8. Claims 1-14 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated DNA encoding the amino acid

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sequence of SEQ ID NO: 2 and methods of using it and plants transformed therewith, does not reasonably provide enablement for an isolated DNA encoding any *Hordeum vulgare* HPPD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 May 2005. Applicant's arguments filed 26 August 2005 have been fully considered but they are not persuasive.

Applicant claims an isolated DNA encoding *Hordeum vulgare* HPPD (hydroxyphenyl pyruvate dioxygenase).

Applicant teaches an isolated DNA from *Hordeum vulgare* encoding the amino acid sequence of SEQ ID NO: 2 and encoding an HPPD enzyme.

Applicant does not teach a genus of isolated DNAs encoding *Hordeum vulgare* HPPD.

Applicant's argument that amending claim 1 to recite "...*Hordeum vulgare*..." overcomes the instant rejection is not found to be persuasive (page 4 of the response filed on 26 August 2005). Applicant does not teach how to identify and isolate all of the claimed DNA sequences because Applicant only gives general guidance for Southern blot analysis, used to isolate a genomic clone of the instant invention (page 23 of the Specification). In addition, Applicant admits that "A knowledge of the HPPD DNA sequence is an absolute prerequisite both...and for increasing the vitamin E synthesis in plants" (page 5 lines 11-14 of the Specification). Hence, it would have required undue trial and error experimentation for one of skill in the art at the time of Applicant's

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invention to isolate all of the DNA sequences that encode a *Hordeum vulgare* HPPD, identify those that are useful, produce expression cassettes and transform plants, identifying those transformed plants that have elevated vitamin E content.

***Allowable Subject Matter***

9. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

10. The claims are free of the prior art, which neither teaches nor suggests an isolated DNA encoding *Hordeum vulgare* HPPD.

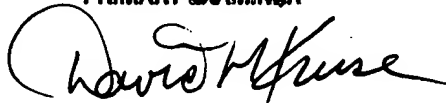
11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (571) 272-0745. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER



David H. Kruse, Ph.D.  
7 November 2005



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13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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